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petition
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*LIMITED TO MATTERS
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***SENIOR COUNSEL

January 4, 2002

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JAN 15 2002

OFFICE OF PETITIONS

Commissioner for Patents
Washington, D.C. 20231

Box Patent Extension

Re: U.S. Patent No. 5,464,864
Issue Date: November 7, 1995
For: **Use of Tetrahydrocarbazone Derivatives as 5HT₁ Receptor Agonists**
Inventors: KING *et al.*
Our Ref: 0623.0900000/EKS/HLK/PSC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17) (*in duplicate*);
2. Five copies of a Patent Term Extension Application Under 35 U.S.C. § 156, with attachments A-F, said attachments including an
 - a. original executed Power of Attorney,
 - b. a copy of a letter from Elan Pharmaceuticals Inc.,
 - c. a copy of U.S. Patent No. 5,464,864 (including a Certificate of Correction),
 - d. a copy of a Patent Maintenance Fee Report,
 - e. a copy of the approved labeling for FROVA™, and
 - f. a Chronology of Significant Activities Undertaken During the Applicable Regulatory Period; and
3. One (1) return postcard.

Commissioner for Patents
January 4, 2002
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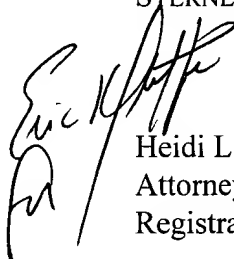
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge the fee of \$1,060.00 and any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

 Reg # 36,688
Heidi L. Kraus
Attorney for Applicants
Registration No. 43,730

EKS/HLK/PSC/lam
Enclosures

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#13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

KING *et al.*

Patent No. 5,464,864

Issued: November 7, 1995

For: **Use of Tetrahydrocarbazone
Derivatives as 5HT₁ Receptor
Agonists****RECEIVED**

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OFFICE OF PETITIONS

Atty. Docket: 0623.0900000/EKS/HLK/PSC

**Patent Term Extension Application
Under 35 U.S.C. § 156**The Honorable Commissioner of
Patents and Trademarks
Washington, DC 20231**Box Patent Extension**

Sir:

Applicant, Vernalis Limited, an English corporation, is the assignee of the entire interest in and to U.S. Patent No. 5,464,864, entitled **Use of Tetrahydrocarbazone Derivatives as 5HT₁ Receptor Agonists** and granted to Francis David King, Laramie Mary Gaster, Alberto Julio Kaufmann and Rodney Christopher Young on November 7, 1995. Applicant, acting through the undersigned attorney, hereby submits this application for extension of the term of U.S. Patent No. 5,464,864 under 35 U.S.C. § 156.

An original executed Power of Attorney, evidencing the undersigned as an attorney authorized to act on behalf of Vernalis Limited, is attached hereto as "Attachment A". An assignment of U.S. Patent No. 5,464,864 to Vernalis Limited, evidencing that it is the owner of the entire interest therein, has been previously recorded in the United States Patent and Trademark Office (USPTO) on November 8, 2001 at Reel 012134, Frame 0353.

The permission for commercial marketing on which this application is based was granted to Elan Pharma. International Ltd. Pursuant to M.P.E.P. § 2752 (8th ed., August 2001), Applicant

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is including as "Attachment B" a letter from Elan authorizing Applicant to rely on Elan's activities before the United States Food and Drug Administration in seeking approval for FROVA™.

The information required by statute and rules is set forth below.

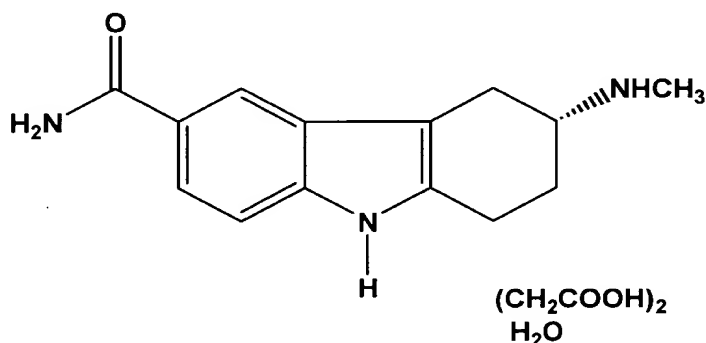
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1. Identification of the Approved Product under 37 C.F.R. § 1.740(a)(1)

The approved product is FROVA™, which contains the active ingredient frovatriptan succinate, having the chemical name R-(+) 3-methylamino-6-carboxamido-1,2,3,4-tetrahydrocarbazole monosuccinate monohydrate and a molecular weight of 379.4. The chemical formula of this compound is $C_{14}H_{17}N_3O \cdot C_4H_6O_4 \cdot H_2O$ and has the structure



2. Identification of the Federal Statute under which Regulatory Review Occurred under 37 C.F.R. § 1.740(a)(2)

The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, Section 505 (21 U.S.C. § 355).

3. The Date of Permission for Commercial Marketing under 37 C.F.R. § 1.740(a)(3)

The approved product received permission for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on November 8, 2001.

4. Active Ingredient Statement under 37 C.F.R. § 1.740(a)(4)

The only active ingredient in FROVA™ is frovatriptan succinate, which has not been previously approved for commercial marketing or use under Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) prior to the approval of NDA 21-006 by the United States Food and Drug Administration on November 8, 2001.

5. Statement of Timely Filing of the Application under 37 C.F.R. § 1.740(a)(5)

This Application for extension of the term of U.S. Patent No. 5,464,864 under 35 U.S.C. § 156 is being submitted within the permitted 60 day period set forth in 37 C.F.R. § 1.720(f). The last day on which the Application can be submitted is January 7, 2002.

6. Identification of Patent for which Extension is Sought under 37 C.F.R. § 1.740(a)(6)

The patent, the term of which this Application seeks to extend, is U.S. Patent No 5,464,864, issued on November 7, 1995, entitled Use of Tetrahydrocarbazone Derivatives as 5HT₁ Receptor Agonists, and naming as inventors Francis David King, Laramie Mary Gaster, Alberto Julio Kaufmann and Rodney Christopher Young. The term of U.S. Patent No. 5,464,864 is otherwise set to expire on November 7, 2012.

7. Copy of Patent for which Extension is Sought under 37 C.F.R. § 1.740(a)(7)

A complete copy of U.S. Patent No. 5,464,864, identified in section number 6 above, is attached as "Attachment C". This Attachment C also includes a Certificate of Correction that corrects errors in U.S. Patent No. 5,464,864.

8. Copies of Disclaimers, Certificate of Corrections, Receipt of Maintenance Fee Payment or Reexamination Certificate Issued under 37 C.F.R. § 1.740(a)(8)

A copy of a Certificate of Correction that was issued in U.S. Patent No. 5,464,864 is enclosed as part of Attachment C. Patent maintenance fees were paid for the fourth year on May 3, 1999. A copy of a Patent Maintenance Fee Report is enclosed as "Attachment D".

9. Statement Showing How the Claims of the Patent for which Extension is Sought Cover the Approved Product Under 37 C.F.R. § 1.740(a)(9)

The operative claims are claims 1-6 of U.S. Patent No. 5,464,864. Claim 1 claims compounds that include the active ingredient in the approved product. Claims 2-5 claim methods of using compounds that include the active ingredient in the approved product. Specifically, claim 2 claims a method of treating conditions wherein a 5-HT₁-like agonist is indicated using compounds that include the active ingredient in the approved product. Claim 3 claims a method of treating a migraine using compounds that include the active ingredient in the approved product. Claim 4 claims a method of treating a cluster headache using compounds that include the active ingredient in the approved product. Claim 5 claims a method of treating a headache associated with vascular disorders using compounds that include the active ingredient in the approved product. Claim 6 claims a pharmaceutical composition comprising compounds including the active ingredient in the approved product, and a pharmaceutically acceptable carrier.

A copy of the approved labeling for the approved product is enclosed as "Attachment E".

Claim 1 reads as follows:

1. A compound of formula (I) which is 3-methylamino-6-carboxamido-1,2,3,4-tetrahydrocarbazole, or a salt, solvate or hydrate thereof.

Claim 1 reads on the drug product as follows:

The approved product, FROVA™, contains the active ingredient R-(+) 3-methylamino-6-carboxamido-1,2,3,4-tetrahydrocarbazole monosuccinate monohydrate, which is a compound within claim 1 of U.S. Patent No. 5,464,864. Hence, claim 1 is directed to the drug product.

Claim 2 reads as follows:

2. A method of treatment of a condition wherein a 5-HT₁-like agonist is indicated, which comprises administering to a subject in need thereof an effective amount of a compound of claim 1.

Claim 2 reads on the drug product as follows:

Claim 2 claims a method of treating a condition wherein a 5-HT₁-like agonist is indicated using a compound within the scope of claim 1. The active ingredient of the approved product is within the scope of claim 1, as set forth above. Hence, claim 2 is directed to a method of using the drug product.

Claim 3 reads as follows:

3. The method according to claim 2 wherein the condition is migraine.

Claim 3 reads on the drug product as follows:

Claim 3 claims a method of treating migraine using a compound within the scope of claim

1. The active ingredient of the approved product is within the scope of claim 1, as set forth above.

Hence, claim 3 is directed to a method of using the drug product.

Claim 4 reads as follows:

4. The method according to claim 2 wherein the condition is cluster headache.

Claim 4 reads on the drug product as follows:

Claim 4 claims a method of treating migraine using a compound within the scope of claim

1. The active ingredient of the approved product is within the scope of claim 1, as set forth above.

Hence, claim 4 is directed to a method of using the drug product.

Claim 5 reads as follows:

5. The method according to claim 2 wherein the condition is headache associated with vascular disorders.

Claim 5 reads on the drug product as follows:

Claim 5 claims a method of treating migraine using a compound within the scope of claim

1. The active ingredient of the approved product is within the scope of claim 1, as set forth above.

Hence, claim 5 is directed to a method of using the drug product.

Claim 6 reads as follows:

6. A pharmaceutical composition comprising the compound according to claim 1, or a physiologically acceptable salt thereof and a physiologically acceptable carrier.

Claim 6 reads on the drug product as follows:

Claim 6 claims a pharmaceutical composition comprising a compound according to claim 1 or a physiologically acceptable salt thereof and a physiologically acceptable carrier. The approved product is a tablet containing, as the active ingredient, R-(+) 3-methylamino-6-carboxamido-1,2,3,4-tetrahydrocarbazole monosuccinate monohydrate, which is within the scope of claim 1. In addition, the tablet contains, among other things, lactose NF, microcrystalline cellulose NF and magnesium stearate NF. Thus, it contains a carrier as defined in the patent. Hence, claim 6 is directed to the drug product.

10. Statement of Relevant Dates to Determine the Regulatory Review Period Under 37 C.F.R. § 1.740(a)(10)

The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

- (a) An Investigational New Drug (IND) Application for frovatriptan succinate was submitted and received by the Department of Health and Human Services on September 30, 1995. It was granted IND No. 48,933 and became effective on November 1, 1995.
- (b) A New Drug Application for frovatriptan succinate was received by the Department of Health and Human Services on January 29, 1999. It was granted NDA No. 21-006.
- (c) This New Drug Application was approved on November 8, 2001.

11. Brief Description of Activities Undertaken During the Regulatory Review Period under 37 C.F.R. § 1.740(a)(11)

A brief description of the activities undertaken during the applicable regulatory review period is attached hereto as "Attachment F". This attachment includes a chronology of the significant activities undertaken by the marketing applicant during the applicable regulatory review period.

12. Statement of Opinion of Eligibility of Patent for Extension under 37 C.F.R. § 1.740(a)(12)

Applicant is of the opinion that U.S. Patent No. 5,464,864 is eligible for extension under 35 U.S.C. § 156 and 37 C.F.R. § 1.720 because it satisfies all of the requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) and 37 C.F.R. § 1.720(a)

U.S. Patent No. 5,464,864 claims a human drug product, frovatriptan succinate, compositions thereof, and methods of use thereof.

(b) 35 U.S.C. § 156(a)(2) and 37 C.F.R. § 1.720(b)

The term of U.S. Patent No. 5,464,864 has never been extended.

(c) 35 U.S.C. § 156(a)(3) and 37 C.F.R. § 1.720(c)

The Application for extension of the term of U.S. Patent No. 5,464,864 is submitted by the authorized attorney of the owner of record in accordance with the requirements of 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740.

(d) 35 U.S.C. § 156(a)(4) and 37 C.F.R. § 1.720(d)

The approved product, FROVA™, was subject to a regulatory review period before its commercial marketing or use.

(e) 35 U.S.C. § 156(a)(5)(A) and 37 C.F.R. § 1.720(e)

FROVA™ has received permission for commercial marketing and use. This permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred.

(f) 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f)

This Application is submitted within the 60 day period beginning on the date the approved product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred.

(g) 35 U.S.C. § 156(a)(1) and 37 C.F.R. § 1.720(g)

The term of U.S. Patent No. 5,464,864 has not expired before the submission of this Application.

(h) 37 C.F.R. § 1.720(h)

To the best of Applicant's knowledge, no other patent term has been extended for the same regulatory review period for the drug product.

13. Length of Extension Claimed under 37 C.F.R. § 1.740(a)(12)

The length of extension of the patent term of U.S. Patent No. 5,464,864 claimed by Applicant is 3 years and 1 day or 1096 days calculated in accordance with 37 C.F.R. § 1.775 as follows:

- (a) The regulatory review period under 35 U.S.C. § 156(g)(1)(B) began on November 1, 1995 (the date the IND became effective) and ended on November 8, 2001 (the date of approval), amounting to a total of 6.03 years or 2200 days, which is the sum of (i) and (ii) below:
 - (i) The period of review under 35 U.S.C. § 156(g)(1)(B)(i) began on November 1, 1995 and ended on January 29, 1999, which is 1186 days or 3.25 years;
 - (ii) The period of review under 35 U.S.C. § 156(g)(1)(B)(ii) began on January 29, 1999 and ended on November 8, 2001, which is 1014 days or 2.78 years;

- (b) The regulatory review period upon which the extension is calculated is the entire regulatory review period as determined in sub-paragraph (13)(a) above (2200 days) less:
- (i) The number of days in the regulatory review period which were on or before the date on which the patent issued (November 7, 1995), which is 7 days, and;
 - (ii) The number of days during which the Applicant did not act with due diligence, which is zero days, and
 - (iii) One half of the number of days remaining in the period in sub-paragraph (13)(a)(i) after subtracting the number of days in sub-paragraphs 13(b)(i) and (13)(b)(ii), which is one half of $(1186 - [7 + 0])$ or 589.5 days;
- which results in a period of $2200 - [7 + 0 + 589] = 1604$ days or 4.40 years.
- (c) The number of days as determined by sub-paragraph (13)(b), when added to the original term, would result in the date of March 30, 2017.
- (d) Fourteen (14) years when added to the date of the NDA Approval Letter (November 8, 2001), would result in the date of November 8, 2015.
- (e) The earlier date as determined by sub-paragraphs (13)(c) and (13)(d) is November 8, 2015.
- (f) Since the original patent was issued after September 24, 1984, the extension otherwise obtainable is limited to not more than five years. Five years, when added to the original expiration date of U.S. Patent No. 5,464,864 (November 7, 2012) results in November 7, 2017.

- (g) The earlier date as determined in sub-paragraphs (13)(e) and (13)(f) is November 8, 2015.

14. Duty of Disclosure Acknowledgment under 37 C.F.R. § 1.740(a)(13)

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

15. Fee Charge under 37 C.F.R. § 1.740(a)(14)

The prescribed fee for receiving and acting upon this application is to be charged to Applicant's Deposit Account 19-0036 as authorized in the attached transmittal letter, submitted in triplicate.

16. Correspondence Information Required by 37 C.F.R. § 1.740(a)(15)

All inquiries and correspondence relating to this application for patent term extension should be addressed to:

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Heidi L. Kraus Reg # 36,688
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Attorney for Applicants
Registration No. 43,730

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